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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,418	07/11/2003	Daniel R. Deakter	20354-0004	7063

25267 7590 02/20/2009

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EXAMINER	
PORTER, RACHEL L	
ART UNIT	**PAPER NUMBER**
3626	

MAIL DATE	DELIVERY MODE
02/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,418	DEAKTER, DANIEL R.	
	Examiner	Art Unit	
	RACHEL L. PORTER	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/25/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 11/25/08 . Claims 1-17 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 8-10, are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, **System makes it easier to link patients to clinical trials** (hereinafter Baldwin) in view of Angiogenesis Weekly, **Clinical Trials; Comprehensive Online Resource Launched** (hereinafter Veritas) and in further view of Colon et al (hereinafter Colon- US 5,991,731)

As per claim 1, Baldwin discloses a system for enrolling patients in a medical study, comprising:

- a database component operative to maintain a medical practice (e.g. hospital) database component and their corresponding plurality of specialties (see paragraph 5), and a clinical studies database component and its corresponding plurality of clinical studies (see paragraph 24);

- a communications component to alert said medical practices (e.g. hospital) to said clinical studies and receive changes to said databases (see paragraph 13); and a
- processor programmed to: update said database components (see paragraph 23); periodically match compatible medical information and medical studies (see paragraphs 13 and 14); and generate reports to matched medical practices in said medical practice database (see paragraph 23).

Baldwin teaches the features of claim 1 as explained above. It is respectfully submitted that a hospital is a location for the practice of medicine. Baldwin does not explicitly disclose matching medical specialties of medical practices with compatible medical studies. However, Veritas teaches matching medical specialties of medical practices (i.e. physicians) with compatible medical studies (see paragraphs 3 and 4). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this matching feature into the system described by Baldwin. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of enhancing the “fuzzy matching” technique disclosed by Baldwin).

Claim 1 has also been amended to further recite: "a coordinator, including a coordinator database component to maintain a clinical studies database and a clinical patient database including non-identifiable information about the plurality of patients, the coordinator including a coordinator communications component, to communicate with

each of the plurality of hospital communications components."Baldwin and Veritas in combination do not expressly disclose a coordinator database as recited.

Colon discloses a coordinator (Figure 1(10)) including a coordinator database component to maintain a clinical studies database and a clinical patient database including non-identifiable information about the plurality of patients (col. 5, lines 25-35), the coordinator including a coordinator communications component, to communicate with each of the plurality of hospital communications components (Figure 1; col. 2, lines 58-col. 3, line 13; col. 5, lines 25-35)

At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin and Veritas in combination with the teaching of Colon to include a coordinator, including a coordinator database. As suggested by Colon, one would have been motivated to include this feature to allow larger studies to be conducted at more diversely distributed locations with lower costs and to communicate data more effectively. (col. 1, line 60-col. 2, line 8)

Claim 1 also has been amended to recite that the system includes: " a plurality of hospital database components;" "a plurality of communications components" and "a plurality of processors." As per the recitation of "a plurality of components" where singular components were previously recited, the courts have broadly held that the duplication of parts is obvious. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). At the the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to further modify the system of Baldwin and Veritas to include a plurality of the recited components with the motivation of allowing larger studies to be

conducted at more diversely distributed locations with lower costs and to communicate data more effectively. As such, these changes do not present a patentable distinction over the applied prior art of record.

As per claim 2, Baldwin Veritas and Colon in combination disclose the system of claim 1 as explained in the rejection of claim 1. Baldwin further discloses:

said hospital database operative to maintain a medical practice database component identifying patients associated with each said medical practice (i.e. physician) in said medical practice database (see paragraphs 12 and 23); said processor programmed to: update said hospital database component with data supplied by said communications component (see paragraph 23); and generate reports to said matched medical practices to include a listing of prospective patients (see paragraphs 13, 14, and 23).

As per claim 3, Baldwin in view of Veritas disclose the system of claim 1 as described above. Baldwin further discloses a searching component for searching said clinical studies database being maintained by a medical practice firm (see paragraph 18); wherein said searching component is adaptable to receive queries from said medical practices via said searching components (see paragraphs 12-14).

Claim 3 also has been amended to recite that the system includes: " a plurality of searching components." As per the recitation of "a plurality of components" where singular components were previously recited, the courts have broadly held that the

duplication of parts is obvious. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). At the the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to further modify the system of Baldwin and Veritas to include a plurality of the recited components with the motivation of allowing larger studies to be conducted at more diversely distributed locations with lower costs and to communicate data more effectively. As such, these changes do not present a patentable distinction over the applied prior art of record.

Claims 8-10 contain substantially similar computerized method limitations to the system limitations recited in claims 1-3 and, as such, are rejected for similar reasons as given above.

4. Claim 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, **System makes it easier to link patients to clinical trials** (hereinafter Baldwin) in view of Angiogenesis Weekly, **Clinical Trials; Comprehensive Online Resource Launched** (hereinafter Veritas), Colon and further in view of Knight, (U.S. Patent Application No. 2002/0099570.)

As per claim 15, Baldwin and Veritas in combination disclose the method of claim 8 as described in the rejection of claim 8. Baldwin further discloses posting a for listing each said medical study in said clinical studies database (see paragraph 24). Baldwin does not explicitly disclose receiving queries from prospective patients via said posting component. However, Knight teaches a clinical trial recruitment system that

includes a component for receiving queries from prospective patients (see paragraph 52). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this feature into the system described by Baldwin. One of ordinary skill in the art would have been motivated to include this feature to provide stronger, more accurate matches of clinical trials to specific patients.

5. Claims 4-6 , 11-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, **System makes it easier to link patients to clinical trials** (hereinafter Baldwin) in view of Angiogenesis Weekly, **Clinical Trials; Comprehensive Online Resource Launched** (hereinafter Veritasr); Colon and further in view of Kraftson et al., (U.S. Patent No. 6,151,581)

As per claim 4, Baldwin and Veritas in combination teach the system of claim 2 as described in the rejection of claim 2. Baldwin does not explicitly teach maintaining a fee database component identifying fees associated with procedures performed by medical specialties; said processor programmed to calculate a total fee to be paid to each said medical practice participating in each said medical study utilizing said fee database component.

Kraftson teaches such fee calculation features (see column 5, lines 7-22, in particular, “practice management/costs data,” and column 13, lines 52-56). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this feature into the system described by Baldwin. As

suggested by Kraftson one of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of better managing physician costs (see column 5, lines 59-62).

As per claim 5, Baldwin in view of Veritas and Kraftson teach the system of claim 4 as described in the rejection of claim 4. Baldwin does not explicitly teach a fee database component operative to maintain a doctor's fee database component identifying fees associated with doctor's procedures as part of said medical studies and an ancillary fee database component identifying fees associated with miscellaneous charges associated with said medical studies; said processor programmed to calculate said total fee from said doctor's fee database component and said ancillary fee database component.

Kraftson teaches maintaining such a fee database component (see column 10, lines 40-54). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this feature into the system described by Baldwin. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of better managing physician costs (see column 5, lines 59-62).

As per claim 6, Baldwin in view of Veritas and Kraftson teach the system of claim 5 as described in the rejection of claim 5. Baldwin does not explicitly disclose generating a billing statement based upon said total fee and a number of patients actually enrolled in one of said plurality of medical studies.

Kraftson teaches such billing features (see column 10, lines 40-54). It would have been obvious to one of ordinary skill in the art of clinical trial matching at the time of the invention to incorporate this feature into the system described by Baldwin. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of better managing physician costs (see column 5, lines 59-62).

Claims 11-14 contain substantially similar computerized method limitations to the system limitations recited in claims 4-6 and, as such, are rejected for similar reasons as given above.

Claim 16 contain substantially similar computerized method limitations to the system limitations recited in claims 1-3 and 11 and, as such, are rejected for similar reasons as given above.

6. Claims 7 and 17 are under 35 U.S.C. 103(a) as being unpatentable over Baldwin in view of Veritas, Colon and in further view of Briegs et al (US 7,054,823).

As per claims 7 and 17, Baldwin and Veritas in combination disclose the limitations of claims 2 and 9 as explained in the rejections of claims 2 and 9, but do not expressly disclose that the processor is programmed to generate a metric of completed components of the medical study or timeline for completion of the study.

Briegs discloses a system and method wherein timelines and deadlines for study milestones are generated. (col. 9, lines 32-48) It would have been obvious at the time

of the Applicant's invention to further modify the teachings of Baldwin and Veritas in combination with the teachings of Briegs to generate timelines and deadlines for the study. As suggested by Briegs, one would have been motivated to include this feature to ensure that the study remains coordinated and well-organized. (col. 1, lines 35-50)

Response to Arguments

7. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's arguments filed 11/25/08 have been fully considered but they are not persuasive.

(A) Applicant has substantially amended the claims and has argued new features regarding these claims. The examiner has provided new grounds of rejection and a new reference to address the newly added limiitations.

(B) Applicant also argues the individual merits of the references and suggests that there is no reason to combine the applied references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner has provided appropriate reference citations, as well as motivations for combining the particular references.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./
Examiner, Art Unit 3626

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626